SPECIAL COMMUNICATION

Comparison of the five 2011 guidelines for the treatment of carotid stenosis

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In 2011, five independent, international guideline committees reported their recommendations for the management of symptomatic and asymptomatic carotid artery stenosis. These included the American College of Cardiology/American Heart Association, the Society for Vascular Surgery, the European Society of Cardiology, the Australasian, and the UK National Institute of Health and Clinical Excellence. As the recommendations of these five guideline committees were based on the same published literature, it would be expected that they are similar, at least to a large extent. Surprisingly, there were considerable differences between the five guidelines regarding the management of both symptomatic and asymptomatic carotid patients. The differences in the recommendations between the five Guideline Committees are analyzed and discussed. (J Vasc Surg 2012;55:1504-8.)

With the introduction and widespread use of carotid artery stenting (CAS), there is an ongoing debate regarding the treatment of choice for symptomatic and asymptomatic carotid artery stenosis. Possibly because of this controversy, three different guideline committees reported their recommendations for the management of symptomatic and asymptomatic carotid stenosis in 2011, namely, the American College of Cardiology/American Heart Association (ACC/AHA) Guidelines,[1] the Updated Society for Vascular Surgery (SVS) Guidelines,[2] and the European Society of Cardiology (ESC) Guidelines.[3] Two other guidelines committees also reported their recommendations in 2011 for the indications for CAS[4] and the role of CAS in the management of asymptomatic carotid stenosis.[5]

It would seem reasonable that these guidelines should be similar because they were all based on the same published literature. However, they differ substantially in several regards. This article discusses the differences between the recommendations of the five guideline committees[1-5] and will also attempt to explain these differences and, where possible, reconcile them.

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PATIENTS WITH SYMPTOMATIC CAROTID ARTERY STENOSIS

The UK National Institute for Health and Clinical Excellence (NICE) guidelines included recommendations only for asymptomatic patients.[5] Therefore, the recommendations of the remaining four guideline committees for symptomatic carotid artery stenosis appear in Table I.[1-4]

The ACC/AHA Guidelines recommend CAS as an "alternative" to carotid endarterectomy (CEA) for the management of symptomatic carotid artery stenosis.[1] This implies that CAS is an "equivalent" therapeutic option to CEA for symptomatic patients and has been interpreted in this way by CAS enthusiasts.[6-8] In symptomatic patients, however, CEA is associated with lower stroke and death rates compared with CAS in all randomized trials to date.[6,7] Therefore, CAS should not be viewed at present as an equivalent therapeutic option to CEA in most symptomatic patients.[6,7] Admittedly, with better patient selection and improved CAS technology (eg, use of flow-reversal or cessation techniques,[9,10] and better stents), CAS may prove to be equal or superior to CEA in certain patient subgroups.[6,7] However, currently this is not the case based on the results of published randomized trials.

The updated SVS[2] and the Australasian[3] guidelines make this point and specifically recommend CAS only for symptomatic patients with tracheal stoma, scarred necks, external beam radiotherapy, previous cranial nerve injury, and other specific conditions, as well as for patients with comorbidities considered to be high-risk candidates for CEA.[2,3] The 2011 SVS Guidelines[2] for the management of carotid stenosis are an update of the 2008 SVS Guidelines[11] and were produced in response to new trial data that have emerged since then. The recommendations of the ESC Guidelines[4] approximate the updated SVS[2] and the Aus-

Table I. Recommendations of the 2011 carotid guidelines for patients with symptomatic carotid artery stenosis

Guidelines	*Recommendation*
ACC/AHA[1]	• CAS is indicated as an alternative to CEA for symptomatic patients at average or low risk of complications associated with endovascular intervention when the diameter of the lumen of the internal carotid artery is reduced by more than 70% as documented by noninvasive imaging or more than 50% as documented by catheter angiography and the anticipated rate of periprocedural stroke or mortality is less than 6% [class I; level of evidence, B]. • Among patients with symptomatic severe stenosis (≥70%) in whom the stenosis is difficult to access surgically, medical conditions are present that greatly increase the risk for surgery, or when other specific circumstances exist, such as radiation-induced stenosis or restenosis after CEA, CAS may be considered [class IIb; level of evidence, B]. • CAS in the above setting is reasonable when performed by operators with established periprocedural morbidity and mortality rates of 4%-6%, similar to those observed in trials of CEA and CAS [class IIa; level of evidence, B].
Revised SVS[2]	• In most patients with carotid stenosis who are candidates for intervention, CEA is preferred to CAS for reduction of all-cause and periprocedural death [grade I; level of evidence, B]. • CAS is preferred over CEA in symptomatic patients with ≥50% stenosis and tracheal stoma, situations where local tissues are scarred and fibrotic from prior ipsilateral surgery or external beam radiotherapy, prior cranial nerve injury, and lesions that extend proximal to the clavicle or distal to the C2 vertebral body [grade II; level of evidence: B]. • CAS is preferred over CEA in symptomatic patients with ≥50% stenosis and severe uncorrectable coronary artery disease, congestive heart failure, or chronic obstructive pulmonary disease [grade II; level of evidence, C].
ESC[3]	• In patients with symptomatic 70% to 99% stenosis of the internal carotid artery, CEA is recommended for the prevention of recurrent stroke [class I; level of evidence, A]. • In symptomatic patients at high surgical risk requiring revascularization, CAS should be considered as an alternative to CEA [class IIa; level of evidence, B]. • In symptomatic patients requiring carotid revascularization, CAS may be considered as an alternative to CEA in high-volume centers with documented death or stroke rate <6% [class IIb; level of evidence, B].
Australasian[4]	• CAS may be considered as a treatment option for patients with symptomatic severe carotid stenosis who are at high risk of stroke, but are surgically unsuitable for CEA, namely postradiation therapy, block dissection of the neck, in situ tracheostomy, recurrent stenosis following previous CEA, severe cervical spine arthritis, surgically inaccessible carotid stenosis (eg, obesity, high carotid bifurcation), contralateral recurrent laryngeal nerve injury, and contralateral internal carotid occlusion. • The overall results of randomized controlled trials indicate that CAS is not as safe as CEA for treatment of symptomatic carotid stenosis for prevention of ipsilateral stroke.

ACC/AHA, American College of Cardiology/American Heart Association; *CAS,* carotid artery stenting; *CEA,* carotid endarterectomy; *ESC,* European Society of Cardiology; *SVS,* Society for Vascular Surgery.

Table II. Recommendations of the 2011 carotid guidelines for patients with asymptomatic carotid artery stenosis

Guidelines	*Recommendation*
ACC/AHA[1]	• Prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (minimum 60% by angiography, 70% by validated Doppler ultrasound), but its effectiveness compared with medical therapy alone in this situation is not well established [class IIb; level of evidence, B].
Revised SVS[2]	• Neurologically asymptomatic patients with ≥60% diameter stenosis should be considered for CEA for reduction of long-term risk of stroke, provided the patient has a 3- to 5-year life expectancy and perioperative stroke/death rates can be ≤3% [grade I; level of evidence, A]. • There are insufficient data to recommend CAS as primary therapy for neurologically asymptomatic patients with 70% to 99% diameter stenosis. In properly selected asymptomatic patients, CAS is equivalent to CEA in the hands of experienced interventionalists with a combined stroke and death rate <3% [grade II; level of evidence, B].
ESC[3]	• In asymptomatic patients with carotid artery stenosis ≥60%, CEA should be considered as long as the perioperative stroke and death rate for procedures performed by the surgical team is <3% and the patient's life expectancy exceeds 5 years [class IIa; level of evidence, A]. • In asymptomatic patients with an indication for carotid revascularization, CAS may be considered as an alternative to CEA in high-volume centers with documented death or stroke rate <3% [class IIb; level of evidence, B].
Australasian[4]	• There is currently no evidence to support CAS as a treatment for asymptomatic carotid stenosis.
NICE[5]	• Current evidence on the safety of CAS placement for asymptomatic extracranial carotid stenosis shows well-documented risks, in particular, the risk of stroke. The evidence on efficacy is inadequate in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.

ACC/AHA, American College of Cardiology/American Heart Association; *CAS,* carotid artery stenting; *CEA,* carotid endarterectomy; *ESC,* European Society of Cardiology; *NICE,* UK National Institute for Health and Clinical Excellence; *SVS,* Society for Vascular Surgery.

tralasian[3] guidelines more closely than the ACC/AHA Guidelines.[1] They provide a weak recommendation for CAS as an alternative to CEA only in symptomatic patients at high surgical risk or in high-volume centers with documented stroke and mortality rates <6%.[4]

PATIENTS WITH ASYMPTOMATIC CAROTID ARTERY STENOSIS

The recommendations of the five guidelines for asymptomatic carotid artery stenosis appear in Table II.[1-5] According to the ACC/AHA Guidelines,[1] CAS might be considered as an option for asymptomatic carotid stenosis (class IIb; level of evidence, B). In contrast, the SVS[2] and the Australasian[3] guidelines indicate that there is currently insufficient evidence to recommend CAS for asymptomatic stenosis. The NICE Guidelines make clear that clinicians wishing to undertake CAS for asymptomatic carotid stenosis should ensure that patients "understand the uncertainty about the procedure's efficacy, the risk of stroke and other complications, and the reasons for advising CAS rather than CEA or BMT alone in their particular case."[5] The ESC Guidelines gave a class IIa recommendation for CEA and a class IIb recommendation for CAS in asymptomatic patients.[3] In addition, the ESC emphasizes that for CAS to be performed in asymptomatic patients, it should be done in high-volume centers with documented stroke and death rates <3%.[3] The NICE Guidelines[5] are in agreement with the ESC Guidelines.[3]

Large multicenter studies have demonstrated that CAS and CEA are associated with similar outcomes in asymptomatic patients.[12,13] However, CAS is more expensive than CEA.[14,15] Furthermore, several recent analyses indicate that best medical treatment (BMT) alone, without the need for CAS or CEA, is sufficient for the management of most asymptomatic carotid patients.[16-18]

The treatment of choice for asymptomatic carotid stenosis therefore still remains uncertain. The results of the Stent-Protected Angioplasty in Asymptomatic Carotid Artery Stenosis II (SPACE-II)[19] study, a three-arm randomized trial comparing CEA vs CAS vs BMT, and perhaps other similar studies, will help to better define the role of BMT in patients with asymptomatic carotid stenosis. However, the results of these trials will not be known for many years, and controversy in this field will continue.

DISCUSSION

A brief discussion of the recommendations of the five guidelines is presented. Regarding symptomatic patients, the updated SVS[2] and the Australasian[4] guidelines clearly recommend CEA over CAS for most symptomatic patients requiring intervention. Both guidelines list specific indications for CAS that apply only to a minority of symptomatic patients. The ESC Guidelines[3] also recommend CEA as the gold standard for symptomatic patients and give a low-strength recommendation for CAS in patients at high surgical risk and in centers with documented stroke/death rates <6%. In contrast, the ACC/AHA Guidelines[1] recommend CAS as an "alternative" to CEA for the management of symptomatic carotid artery stenosis.

A possible explanation of the recommendations of the ACC/AHA Guidelines[1] may be that the ACC/AHA was misled by the results of the Carotid Revascularization Endarterectomy vs Stenting Trial (CREST).[12] CREST compared CEA with CAS in both symptomatic and asymptomatic patients and concluded that "for 2,502 patients over a median follow-up period of 2.5 years, there was no significant difference in the estimated 4-year rates of the primary end point between the stenting group and the endarterectomy group (7.2% and 6.8%, respectively; hazard ratio [HR] with stenting, 1.11; 95% confidence interval [CI], 0.81-1.51; $P = .51$)."[12]

The primary end point in CREST, however, included the incidence rates of stroke, myocardial infarction, or death from any cause.[12] When the percentages were analyzed separately for each end point, CAS was associated with a nonsignificant (due to small numbers; $P = .18$) more than twofold higher risk for periprocedural death (9 CAS vs 4 CEA deaths; HR, 2.25; 95% CI, 0.69-7.30), a significant ($P = .01$) an almost twofold increased risk for any periprocedural stroke (52 CAS vs 29 CEA strokes; HR 1.79; 95% CI, 1.14-2.82), and a highly significant more than twofold increased risk for minor ipsilateral stroke (37 CAS vs 17 CEA episodes; HR, 2.16; 95% CI, 1.22-3.83; $P = .009$) compared with CEA. However, patients undergoing CAS suffered fewer myocardial infarctions compared with those undergoing CEA (14 vs 28, respectively; HR, 0.50; 95% CI, 0.26-0.94; $P = .03$).[12] This difference balanced the difference in strokes and produced the apparent "equivalence in the overall primary end point." An analysis and interpretation of the CREST results is provided in greater detail elsewhere.[20]

The revised SVS,[2] Australasian,[4] and NICE[5] guidelines conclude that there is currently insufficient evidence to recommend CAS for asymptomatic patients. In contrast, the ESC[3] and the ACC/AHA[1] guidelines both provide recommendations that may be misinterpreted to extend the use of CAS in these patients. More specifically, the ESC guideline provides a weak recommendation for CAS as an alternative to CEA in high-volume centers with documented death or stroke rate <3%.[3] Similarly, although the ACC/AHA guideline mentions that the effectiveness of CAS compared with BMT is not yet well-established, it still recommends that prophylactic CAS might be considered in "highly selected" asymptomatic patients (ie, patients at high surgical risk).[1] A list of these selected patients is provided. It is worth mentioning that among the patients considered "high-risk" are individuals with ≥50% contralateral carotid stenosis.[1]

Before the SVS endorsed the ACC/AHA Guidelines,[1] the SVS Executive Committee raised the issue of rewriting the word "alternative."[21] This was, however, considered counterproductive because the document would have to be returned to all 16 sponsoring societies for altering a single word.[21] Subsequently, the SVS published its updated guideline for the management of carotid artery disease,

where it is clearly recommended that "in most patients with carotid stenosis who are candidates for intervention, CEA is preferred to CAS for reduction of all-cause stroke and periprocedural death (grade I; level of evidence, B)."[2] Furthermore, the SVS clearly stated that CEA is the treatment of choice for patients with symptomatic carotid stenosis who are at acceptable risk for surgery.[21]

The diversity in the recommendations of the five 2011 guidelines[1-5] suggests that the optimal management of symptomatic and asymptomatic carotid stenosis is still a controversial subject. A likely reason for the differences seen in the five 2011 guidelines may be possible bias in the interpretation of the existing trial results. Furthermore, there seems to be a difference in perception or precise content between some "multispecialty"[1] vs "single-specialty"[2,4] documents; single-specialty documents[2,4] seem to be more definitive than "multispecialty" ones (eg, the ACC/AHA Guidelines[1]).

Obviously, additional trials are needed to resolve these controversies. These future trials will have to be designed with care to provide information that will clearly define the role for CAS in symptomatic and asymptomatic patients. For example, CAS will likely get better results with its restriction to younger patients (age <70 years),[12] use of better stents (membrane or mesh-covered), and with wider use of better embolic protection devices. Furthermore, with asymptomatic disease, we need to identify patients at high risk of stroke so that they can be treated without subjecting most carotid stenosis patients to CAS or CEA. Future trials in asymptomatic patients comparing CAS, CEA, and BMT should possibly be restricted to such high-risk patients.

CONCLUSIONS

The uncertainty in the role of BMT in asymptomatic patients, the disagreement in the five most recent guidelines, and the likelihood of ongoing and future improvements in CAS make it possible that the 2011 carotid guidelines may turn out to be misleading or incorrect. As shown by current evidence, the updated SVS[2] and the Australasian[4] guidelines address the issue of the proper management of symptomatic and asymptomatic carotid patients in the most optimal way. Nevertheless, these guidelines may also need to be revised in the future as improvements in CAS occur and the results of randomized controlled trials emerge regarding the efficacy of CAS vs CEA vs BMT alone in asymptomatic patients.

AUTHOR CONTRIBUTIONS

Conception and design: KP
Analysis and interpretation: KP, FV
Data collection: KP
Writing the article: KP, DM, FV
Critical revision of the article: KP, DM, FV
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INVITED COMMENTARY

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The debate about the appropriate management of carotid bifurcation disease not only continues but has intensified related to a number of events over the past 18 months. These include (1) publication of the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST) trial results, including the important follow-up studies emphasizing the clear-cut differences in symptomatic vs asymptomatic patients with regard to periprocedural complications of stroke and death; (2) publication of multiple guideline documents during the calendar year 2011, as reviewed by the authors; (3) increasing emphasis in some quarters to the claim that best/modern medical therapy is sufficient treatment (ie, without any intervention) in asymptomatic patients; and, (4) further considerations by the Centers for Medicare & Medicaid Services (CMS) in the form of a CMS Medical Evidence Development and Coverage Analysis Committee (MEDCAC) meeting that was held January 25, 2012. The MEDCAC panel heard testimony on multiple viewpoints from a variety of stakeholders involved in the management of carotid disease. The Society of Vascular Surgery (SVS) was very involved at a high level in the CMS MEDCAC and provided its views regarding this issue.

The authors appropriately emphasize that single-specialty practice guidelines tend to be more definitive and declarative than those produced by consensus in multispecialty-type documents. The authors emphasize[1] the prior discussions SVS held with the American College of Cardiology/American Heart Association Guidelines principal authors (Drs Brott and Halperin) and the basis of those conversations resulting in SVS endorsement of this very comprehensive document. Just as has been true in the multiple discussions about the CREST trial results, comparison of the guideline documents reviewed by the authors is very much an "eye of the beholder" phenomenon.

In their article, the authors cite such obfuscation when they review, for example, a recommendation from one of the documents, which characterizes the use of carotid artery stenting (CAS) in asymptomatic patients as "might be reasonable in highly selected patients . . . , but its effectiveness compared to best medical therapy is not well studied." Such a recommendation is obviously open to any extremes of interpretation but perhaps reflects the fact that management of asymptomatic patients is both controversial and the subject of a highly polarizing debate among those who hold different viewpoints.

It is important to emphasize, as the authors have done, that guidelines published in 2011 can only reflect the best available and high-level evidence (ie, that gleaned from well-performed, randomized, clinical trials). Accordingly, the SVS guidelines support carotid endarterectomy in properly selected asymptomatic patients (largely based on the impressive data in the Asymptomatic Carotid Surgery Trial (ACST). Alternatively, the vocal claim that optimal modern medical therapy produces equivalent or better results is based on a compendium of studies from an evidence base that can be collectively criticized as containing many patients with degrees of asymptomatic stenosis for whom intervention would never be recommended by current SVS practice guidelines.

Although I agree with the authors that the guidelines they have reviewed can be considered to have very different recommendations, they can also be considered to have very similar recommendations, depending on how one chooses to interpret words like "alternative." At the other end of the spectrum, in asymptomatic patients, the United Kingdom National Institute of Health and Clinical Excellence guidelines, for example, unequivocally state that CAS for asymptomatic patients should only be performed in the context of well-designed and approved clinical trials.

No doubt, we are once again in the midst of great controversy in the management of, in particular, asymptomatic carotid stenosis and the overall role of CAS. It is worth emphasizing that SVS has identified the management of asymptomatic carotid stenosis as its single most important clinical research priority. It is also clear that management of carotid disease has been a core element of vascular surgery practice ever since the original description of the pathoanatomic relationship between carotid atherosclerosis and stroke in 1951. Sixty years later, the debate continues, and vascular surgeons must remain involved in the study of all of these controversies moving forward.

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